

## **EXHIBIT B**

## II. Mylan's ANDA For Nifedipine XL 30 mg Is No Longer A Paragraph IV ANDA

By definition, a paragraph IV certification is one which alleges that a patent covering the reference listed drug is invalid, will not be infringed by the generic product that is the subject of the ANDA, or is unenforceable. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). In short, a paragraph IV ANDA, by definition, must challenge a blocking patent. In the absence of such a challenge, the ANDA is not a paragraph IV ANDA.

In this case, Mylan's paragraph IV patent challenge on nifedipine XL 30 mg resulted in a patent infringement lawsuit against Mylan by the patent holder and NDA holder (Bayer AG and Pfizer). Had Mylan won that lawsuit, it would have been legally free and clear to market its own generic nifedipine XL 30 mg product – representing, in effect, a victorious culmination of the patent challenge. Had Mylan lost, it would have been forced to await patent expiration before receiving effective approval of its ANDA. Accordingly, Mylan would have been required to amend its patent certification to a paragraph III certification, signifying that it was no longer challenging the patent. Alternatively, had Mylan never been sued at all within the applicable 45-day window, its ANDA would have been eligible for effective approval immediately upon completion of substantive review without regard to the patent, allowing Mylan to market the product while still, in effect, maintaining its challenge to the patent.

Mylan's settlement with Pfizer, however, avoided any of these outcomes. Instead, that settlement resulted in an agreed dismissal of the lawsuit without judicial resolution of the patent challenge. And through this agreed dismissal, Mylan has dropped its challenge to the patent that was the subject of the case. As a result, the basis for Mylan's paragraph IV certification – its challenge to the patent – has disappeared. Mylan's ANDA for nifedipine XL 30 mg is therefore no longer entitled to be treated as a paragraph IV ANDA.<sup>1</sup>

As a necessary consequence of that change in status, Mylan is no longer eligible for 180-day exclusivity for its nifedipine XL 30 mg ANDA. Only an ANDA “containing” a paragraph IV ANDA is eligible for the 180-day exclusivity, 21 U.S.C. § 355(j)(5)(B)(iv). It follows that once an ANDA ceases to contain a paragraph IV certification, it is no longer eligible for that exclusivity.

This conclusion is not only consistent with the language of the statute, but also with the policy underlying the statute. As FDA itself has acknowledged, 180-day exclusivity “can be interpreted as a reward not only for the benefit provided to subsequent ANDA applicants but for the benefit to the public of removing an obstacle to competition . . . . Therefore, the 180-day

---

<sup>1</sup> FDA discussed this issue in the preamble to its August 1999 proposed rule on 180-day exclusivity; in that discussion, the agency neither rejected nor accepted the view that a settlement renders a paragraph IV applicant ineligible for exclusivity, but merely stated that it believed its proposed “triggering approach” was preferable. 180-Day Exclusivity for Generic Drug Applications, 64 Fed. Reg. 42,873, 42,880 (1999).

period is available to the applicant who resolves an issue of patent coverage . . . .”<sup>2</sup> In this case, Mylan has provided no benefit either to subsequent generic applicants nor to the public, has done nothing to “remove an obstacle to competition” – in fact, quite the contrary – and has not resolved any issue of patent coverage. It should therefore not benefit from the reward of 180-day exclusivity.

Likewise, it is universally accepted that the 180-day exclusivity clause was never intended to create opportunities for drug companies to indefinitely obstruct the market entry of generic drugs by entering into commercial arrangements which, like the Mylan-Pfizer deal, prevent the 180-day period from ever being triggered. As FDA stated in the preamble to last year’s proposed rule on the 180-day exclusivity:

Licensing agreements and other arrangements between an innovator company and the generic drug company who is the first ANDA applicant to file a paragraph IV certification can be of considerable financial benefit to the companies involved, but also may contribute to delayed generic competition by forestalling the beginning, or triggering, of the 180-day exclusivity period. These arrangements can create almost insurmountable barriers to the final approval and marketing of generic drug products that are otherwise ready for final approval. These barriers thwart a major congressional goal underlying the passage of the Hatch-Waxman amendments.<sup>3</sup>

The petitioner respectfully submits that in the case at hand, the means of surmounting the barrier that Mylan and Pfizer have tried to create by their settlement deal are readily at hand in the law itself, and in fact are mandated by that law. Under the circumstances presented by this deal, Mylan’s ANDA is in reality no longer one that “contains” a certification challenging the patent – regardless of which piece of paper physically resides in the ANDA file – because by definition, a generic applicant that has settled with the patent holder in a manner that results in no generic product reaching the market is no longer challenging the patent.<sup>4</sup> Accordingly, the

<sup>2</sup> Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,895 (1989) (preamble to proposed rule).

<sup>3</sup> Id. at 42,874-42,875 (emphasis added). Similarly, as the court held in Mylan Pharmaceuticals, Inc. v. Henney, 94 F. Supp. 2d 36, 53 (D.D.C. 2000), commenting on a deal very similar to the Mylan-Pfizer deal at issue here:

Courts are advised that statutes should not be interpreted so as to create anticompetitive effects [cites omitted]. . . . Hatch-Waxman [is] intended to provide an *incentive* for drug companies to explore new drugs, not a market “windfall” for crafty, albeit industrious, market players.

<sup>4</sup> Mylan and Pfizer have publicly asserted that their settlement deal does not prevent Mylan from marketing its own 30 mg nifedipine XL product, but that any decision not to do so is Mylan’s alone. However, whether or not this is true in a narrow technical sense – and it is impossible to know given that Mylan and Pfizer have concealed the terms of their deal – it is highly unlikely that Pfizer would have agreed to the deal if it expected Mylan to market its own 30 mg generic product, thus opening the entire nifedipine market to generic competition (precisely the situation the deal appears intended to avoid). Indeed, under the circumstances of this deal, it would make no sense whatsoever for Mylan to market its own nifedipine 30 XL and face the possibility of damages for patent infringement that could far exceed any net income Mylan might receive from such marketing, when it can safely sell Procardia XL

petitioner calls upon FDA to recognize that Mylan has relinquished its paragraph IV patent challenge by its deal with Pfizer and has therefore rendered its nifedipine XL 30 mg ANDA ineligible for the 180-day exclusivity. This decision could be given effect either by requiring Mylan to amend its certification to a paragraph III, or simply by ceasing to treat Mylan's ANDA as a paragraph IV ANDA eligible for the 180-day exclusivity, opening the way for immediate effective approval of competing generic products.<sup>5</sup>

### III. The Mylan-Pfizer Deal Constitutes Commercial Marketing And Has Therefore Triggered the 180-Day Exclusivity

Whatever its outward form, the essence of the Mylan-Pfizer deal is that Mylan has committed itself not to market its own 30 mg generic nifedipine XL product in exchange for valuable consideration, namely Pfizer's dropping of its patent infringement lawsuit against Mylan and licensing to Mylan of marketing rights to Procardia XL as an authorized "generic." Of course, Mylan and Pfizer, having observed the antitrust difficulties other companies have found themselves in over explicit agreements to withhold generic products from the market, have been careful to avoid any such explicit agreements. But, as noted above, it takes very little insight to understand that the deal's net effect – and underlying design – is that Mylan will in fact keep its own generic product off the market, whether or not it is explicitly bound to do so.

Thus, Mylan has in a very real sense bargained away the rights to its own generic product under its 30 mg nifedipine XL ANDA in exchange for commercial consideration. Because this is the essence of commercial marketing, FDA should recognize that the commercial marketing trigger of the 180-day provision, 21 U.S.C. 355(j)(5)(B)(iv)(I), was activated on the day the deal was struck, March 2, 2000, and will accordingly expire on August 29, 2000. Alternatively, FDA should recognize that "commercial marketing" took place on the date the Mylan authorized "generic" was introduced to the market pursuant to the Mylan-Pfizer deal, such that Mylan's claim to exclusivity will expire 180 days after that date.

### ***C. Environmental Impact***

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

### ***D. Economic Impact***

---

as an "authorized" generic. Thus, whatever the facial terms of the deal, its practical effect is to preclude Mylan from marketing its own product under its ANDA.

<sup>5</sup> Cf. 21 C.F.R. § 314.94(a)(12)(viii)(C) ("an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate") (emphasis added). Although this regulation is cast in terms of the period prior to approval of the application, there is no reason why its underlying logic should not apply equally to the period after approval. In any event, an applicant who learns that any material element of a pending or approved application is no longer accurate has a moral and legal duty to correct its application accordingly. Cf. 21 U.S.C. § 355(e); 21 U.S.C. § 314.150(a)(2)(iv) (requirement that FDA move to withdraw the approval of any application or abbreviated application found to contain any untrue statement of material fact).

This information will be provided upon request.

*E. Certification*

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Deborah A. Jaskot".

Deborah A. Jaskot  
Sr. Director, Regulatory Affairs